IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORNERSTONE BIOPHARMA INC., *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 13-cv-1275 (GMS)
	)	
EXELA PHARMA SCIENCES LLC, *et al.*,	)	
	)	
Defendants.	)	
	)	

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 7,612,102; 7,659,290; 7,659,291 and 8,455,524

After having considered the submissions of the parties, and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 7,612,102 ("the '102 patent"); 7,659,290 ("the '290 patent"); 7,659,291 ("the '291 patent"); and 8,455,524 ("the '524 patent") (collectively, the "patents-in-suit"):

1. The term "a pre-mixed aqueous solution" is construed to mean "a ready-to-use aqueous solution that is already mixed from the point of manufacture and is stable at room temperature for 6 months or longer."[1]

2. The term "buffer" is construed to mean "a system capable of maintaining the pH within an optimal pH range."[2]

[1] The court adopts the Patent Trial and Appeal Board's construction of this term. *See Sandoz Inc. v. EKR Therapeutics, LLC*, Case IPR2015-00006, Paper No. 20, at *6–9 (P.T.A.B. Apr. 24, 2015) (Decision, Denying *Inter Partes* Review).

[2] The defendants, Exela Pharma Sciences LLC, Exela Pharmsci, Inc., and Exela Holdings, Inc. (collectively, "Exela"), suggest the court construe this term to mean "component of the composition (or aqueous solution) separate and distinct from nicardipine hydrochloride, tonicity agent, cosolvent, water and/or pH adjuster that has sufficient buffering capacity to maintain an optimal pH range throughout the shelf-life of the product." (D.I. 60 at 9.) The plaintiffs, Chiesi USA, Inc., Cornerstone Biopharma, Inc., and EKR Therapeutics, LLC (collectively, "Chiesi") propose this term be construed to mean "a system capable of maintaining the pH within an optimal pH range." (D.I. 52 at 16.)

Exela argues that Chiesi's proposed construction is improper because it encompasses compositions in which the buffer would not be a separate and distinct component of the composition and ignores that the buffer must maintain the optimal pH range throughout the shelf life of the product. Upon review of the intrinsic evidence, the court finds that the patents do not require that a "buffer" be "separate and distinct" from other components. There is no evidence that the patents preclude one component from also acting as another component or serving more than one purpose. As such, the court adopts Chiesi's proposed construction.

3. The term "buffer in an amount to maintain pH from about 3.6 to about 4.7" is construed to mean "a system capable of maintaining the pH within an optimal pH range in an amount to maintain pH from about 3.6 to about 4.7."[3]

4. The term "one year or three months 'at room temperature'" is construed to have its plain and ordinary meaning."[4]

Dated: July 9, 2015

UNITED STATES DISTRICT JUDGE

[3] *See supra* note 2.

[4] Upon review of the specification and claim language, the court determines that a person having ordinary skill in the art would understand this term. *See Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1119 (Fed. Cir. 2002).

The court rejects Chiesi's assertion that the intrinsic evidence confirms that the claimed limitations referring to potency and stability must be based on full-term data. The patents-in-suit do not state or suggest that accelerated testing is inappropriate or should not be used to evaluate stability. Specifically, Example 6 of the '102 patent concludes that "[b]ased on the accelerated stability data at 40 and 45 C., . . . formulations should be stable at room temperature for at least 12 months." ('102 Patent, JA at A-17, col. 17:59–62.) Similarly, Example 4 discusses a stability comparison that was conducted under accelerated conditions. ('102 Patent, JA at A-16, col. 15:66–16:4.) Furthermore, whether or not accelerated testing data meets the "for one year at room temperature" or "for three months at room temperature" limitation is a question of fact for the factfinder to resolve, not a question of claim construction.